Device Classification

Marjorie Shulman
Director, Premarket Notification (510(k)) Program

December 12, 2013

Stair-Climbing and Mechanical Wheelchairs

What Is the Purpose of This Panel Meeting?

To provide input to FDA on the classification of stair-climbing and mechanical wheelchairs and whether FDA should reclassify or maintain them in Class III and Class I (reserved), respectively.

What Are the Device Classes?

- Classified based on controls necessary:
  - Class I - General Controls
  - Class II - General and Special Controls
  - Class III - Premarket Approval
- A device should be placed in the lowest class whose level of control provides reasonable assurance of safety and effectiveness

What Are General Controls?

- General Controls Include:
  - Prohibition against adulterated or misbranded devices,
  - Good Manufacturing Practices (GMPs),
  - Registration of manufacturing facilities,
  - Listing of device types,
  - Recordkeeping, etc.

What Are Special Controls?

Special Controls include:

- Performance standards
- Postmarket surveillance
- Patient registries
- Development and dissemination of guidelines, etc.

What Are Class I Devices

- Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness

Class I devices typically require no FDA premarket review prior to being marketed; class I devices are also typically exempt from many quality system requirements (design controls)

What Are Class I Devices? (cont)

- Devices which cannot be classified into Class III:
  - Because they are not life sustaining, life supporting, of substantial importance in preventing impairment of public health, and
  - Because they do not present a potential unreasonable risk of illness or injury
- Devices which cannot be classified into Class II:
  - Because insufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness

What Does it Mean to be a Class I (reserved) Device?

- In 1997, FDAMA amended Section 206 of FD&C Act to define that all Class I devices are exempt from the requirement of premarket notification, unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury ("reserved" criteria).
- Mechanical wheelchairs were determined to meet the reserved criteria and remain subject to the premarket notification requirement.

What Are Some Examples of Class I Devices?

- General Manual Orthopedic Surgical Instruments
- Adhesive Bandages
- Crutches
- Liquid Bandage (reserved)
- Limb Orthosis for Finger Sucking (reserved)

What Are Class II Devices?

- Cannot be classified into Class I:
  - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and
  - for which there is sufficient information to establish special controls to provide such assurance
- Class II devices typically require premarket notification to FDA (i.e., a 510(k)) prior to being marketed

What Does it Mean to be Class II, Exempt?

- FDA may determine that the safety and effectiveness of a Class II device type can be assured without submission of a 510(k) prior to marketing, and “exempt” manufacturers from the premarket notification requirement.
- Class II devices exempted from premarket notification remain subject to any special controls and manufacturers are required to maintain evidence to support their compliance with the special controls as part of their design history files.

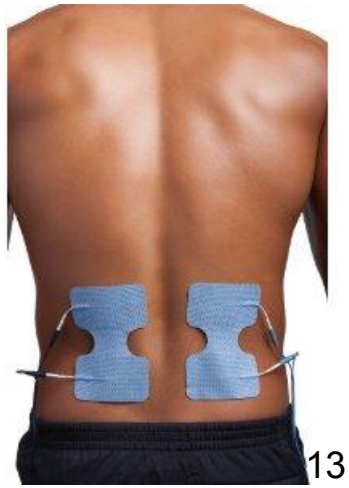
What Does it Mean to be Class II, Exempt? (cont.)

- Based on consideration of several factors:*
  - The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials;
  - Characteristics of the device necessary for its safe and effective performance are well established;
  - Changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and
  - Any changes to the device would not be likely to result in a change in the device's classification.

*Refer to FDA's Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080199.pdf).

What Are Some Examples of Class II Devices?

- Powered stairway chair lift (exempt)
- Permanently mounted wheelchair platform lift (exempt)
- Powered muscle stimulators
- Anterior cervical plates



How Are Special Controls Used?

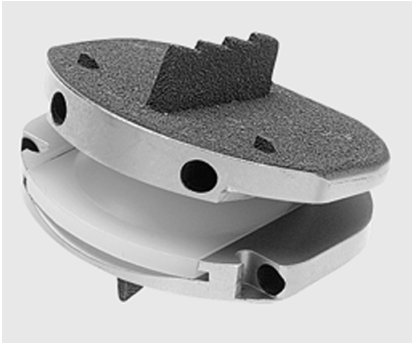
- As an example, spinal cages were reclassified from Class III to Class II (special controls)
- FDA issued a special controls guidance to mitigate risks to health:
  - Biocompatibility testing
  - Material characterization
  - Mechanical testing
  - Sterility
  - Labeling (warnings, precautions, adverse effects, etc.)
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

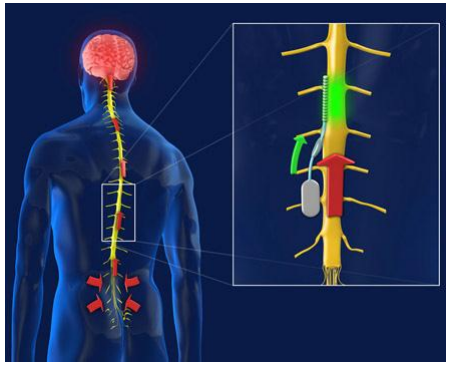
What Are Class III Devices?

- Cannot be classified into Class II because:
  - insufficient information exists to determine that general and specials controls are sufficient to provide reasonable assurance of the safety and effectiveness, and
  - The devices are:
    - life sustaining and/or life supporting, or
    - of substantial importance in preventing impairment of human health; or
    - presents potential unreasonable risk of illness or injury
- Class III devices typically require premarket approval (PMA) prior to being marketed

What Are Some Examples of Class III Devices?

- Total Artificial Disc Replacements
- Spinous Process Spacers for Non-fusion
- Implanted Neurostimulators

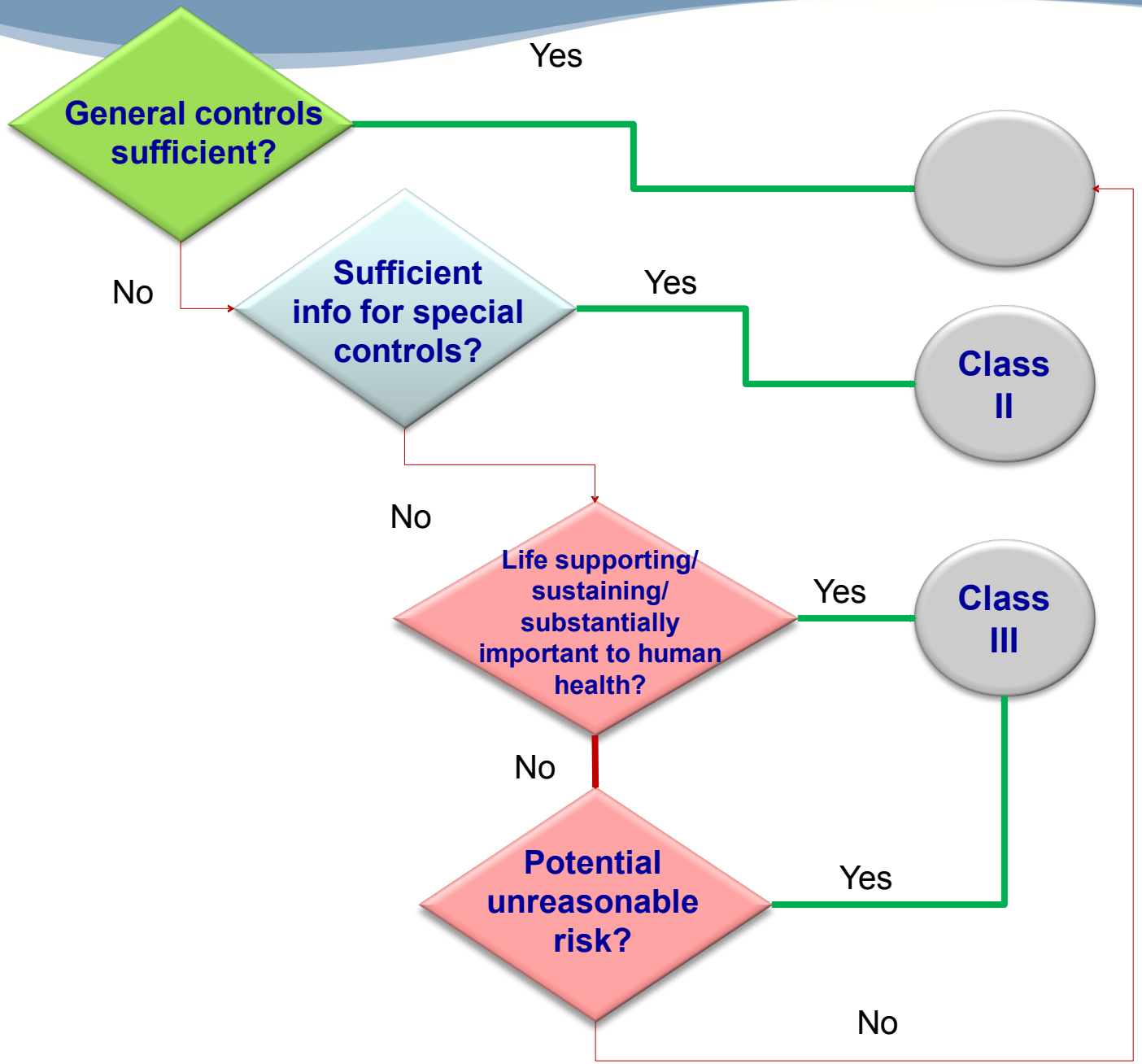




What Is the Classification Process?

Recent legislation (FDASIA) has affected the classification of medical devices and FDA must now:

- Publish a proposed order announcing our proposed classification and seek public comment
- Hold a panel meeting if classifying or reclassifying a device type
- Consider comments and all available information, including panel recommendations, prior to issuing a final order finalizing the classification of the device type


General controls sufficient?
Yes
No
Sufficient info for special controls?
Yes
Class II
No
Life supporting/ sustaining/ substantially important to human health?
Yes
Class III
No
Potential unreasonable risk?
Yes
No

What We Need from the Panel

- Input on classification of the device(s) that are the subject of the Panel session
- Input should include:
  - An identification of the risks to health (if any) presented by the device
  - Whether the device is life-supporting/life-sustaining, of substantial importance in preventing impairment to human health, or presents a potential unreasonable risk of illness or injury
  - Whether sufficient information exists to develop special controls
  - Identification of special controls

What Will Happen After This Panel Meeting?

- FDA will consider the available evidence, including the input of this panel and the public comments
- FDA may issue a proposed order, proposing reclassification of the device(s) and seeking public comment
- FDA may issue a final order identifying the appropriate class